

## **REMARKS**

Applicant respectfully requests consideration of the subject application as amended herein. This Amendment is submitted in response to an Office Action mailed on October 27, 2003. Claims 15, 16, 18, 20, 25-29 and 33 are rejected. Claim 20 has been amended to correct the lack of antecedent and claims 18 and 33 have been amended to correct minor informalities. No new matter has been added. Claims 34-35 have been added.

The Examiner has withdrawn claims 17, 19 and 21-24 as being drawn to a non-elected species.

### **35 U.S.C. § 112, second paragraph**

Claim 20 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 has been amended to correct the indefiniteness.

### **35 U.S.C. § 103(a)**

Claims 15-16, 18, 20, 25-29 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Udipi, et al, (Modification Of Inflammatory Response To Implanted Biomedical Materials In Vivo By Surface Bound Superoxide Dismutase Mimics, hereinafter “Udipi”), in view of Rupp, (U.S. Patent No. 5,451,428, hereinafter “Rupp”) or Kolluri, et al. (U.S. Patent No. 5,962,138, hereinafter “Kolluri”). As discussed below, the pending claims are patentable over the above reference.

The Examiner stated that Udipi discloses treating a biomedical material with superoxide dismutase mimic (SODm) and Rupp and Kolluri disclosed the use of plasma polymerization to provide good bonding with chemical or pharmaceutical agents. The Examiner argued that it would have been obvious for one of ordinary skill in the art to combine Rupp or Kolluri with Udipi to arrive to Applicant's claims 15-16, 18, 20, 25-29 and 33 .

Applicant respectfully disagrees and submits that Udipi, Rupp, and Kolluri, alone or in combination cannot make obvious claims 15-16, 18, 20, 25-29 and 33.

The law requires that, to prevent the use of hindsight, the Examiner "must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F. 3d 1350, 1359 (Fed. Cir. 1998). (See also MPEP 2141 and 2145). The Examiner bears the burden of proving an obviousness type rejection based on findings of fact and not based on conclusive statements. In re Dembiczak, 175 F. 3d 994 (Fed. Cir. 1999). Adequate findings of fact can come from several sources. Id. The motivation to combine reference must be found in the cited references themselves. Id. Alternatively, the PTO may establish that one of ordinary skill in the art could have been motivated to combine the references with articulated findings of fact regarding 1) the level of skill in the art; 2) the relationship between the fields of the cited art; and 3) the particular features of the prior art references that would motivate one of ordinary skill in the Applicant's particular art to select elements disclosed in references from a wholly different field. Id.

Udipi pertained to surface treatment for biomedical devices involving covalent

conjugation of SODm.

Rupp pertained to a method that uses plasma polymerization on a medical device to improve attachment of a biological coating to the surface of the medical device. As stated in Rupp at column 2, lines 39-50, the method includes steps of exposing the medical device to chemical agent consisting of monomer molecules in a gaseous state, which are chemically combined with functional groups. Electromagnetic waves are irradiated into the chemical agent and/or onto the surface of the medical device until the molecules of the chemical agent constitute a functional polymer on the surface of the medical device. A biological coating is then applied to the polymerized monomer surface. The method in Rupp is for a biological coating that is sometimes referred to as bioactive or antithrombogenic coating. Further, coatings suited for this purposes are well known in the art such as heparin-based coating, phosphorylcholine, or polyester. (See Rupp, column 1, lines 46-57).

SODm is not a biological material. An SODm coating cannot be considered a biological coating discussed in Rupp. The few biological coatings discussed in Rupp include heparin and phosphocholine. Heparin is a naturally occurring biopolymer, which affects antithrombolytics by preventing platelet adhesion (phosphocholine) and by preventing platelet activation (heparin). Such biological coating also prevents platelet adhesion.

SODm is a man-made or synthetic material that converts superoxide to water and oxygen and prevents the conversion of nitric oxide to peroxynitrate (which is the result of the conversion of nitric oxide with superoxide).

Therefore, using plasma polymerization to improve adhesion of a biological

coating that is anti-thrombogenic to a medical device does not teach, suggest, or motivate one of ordinary skill in the art to use plasma polymerization for SODm bonding to a plasma polymerized layer on a medical device.

Applicant respectfully submits that there are no reasons that a skilled artisan confronted with the same problems as the inventor and with no knowledge of the claimed invention would select the elements from Udipi and Rupp and combine them as claimed in claims 15-16, 18, 20, 25-29 and 33. Udipi did not suggest or discuss the bonding of SODm to a medical device in conjunction with plasma polymerization. Rupp discussed only using plasma polymerization for a biological coating naming two examples heparin and phosphorylcholine. The biological coating discussed in Rupp is an anti-thrombogenic coating. SODm is a synthetic or man-made material. There is no teaching or suggestion in Rupp to use plasma polymerization with an agent such as SODm. SODm and heparin or phosphorylcholine are sufficiently different such that successful coating of heparin or phosphorylcholine on a medical device using plasma polymerization does not suggest or motivate one of ordinary skill in the art to use the same for SODm. There is also no relationship between a biological coating such as heparin and phosphorylcholine and a non-biological material in the form of SODm.

Thus, it is not obvious for one of ordinary skill in the art to combine Udipi and Rupp to derive to claims 15-16, 18, 20, 25-29 and 33.

With respect to Kolluri, Kolluri pertained to forming a film on a substrate to create a three-dimensional functional film network comprising a plurality of radio frequency discharge plasma film layers. The three-dimensional film networks include functional groups located either on the periphery or both the periphery and interstitial

spaces of the networks to provide an increase surface function density. (See Kolluri Abstract and col. 5, lines 9-32). Applicant respectfully submits that there are no reasons that a skilled artisan confronted with the same problems as the inventor and with no knowledge of the claims invention would select the elements from Udipi and Kolluri and combine them as claimed in claims 15-16, 18, 20, 25-29 and 33. Udipi did not suggest or discuss the bonding of SODm to a medical device in conjunction with plasma polymerization. Kolluri discussed only using plasma polymerization to increase surface function density and made no suggestion or teaching to using plasma polymerization for bonding SODm to a medical device. Thus, the motivation to combine Udipi and Kolluri cannot be said to be found in the references themselves.

Thus, it is not obvious for one of ordinary skill in the art to combine Udipi and Kolluri to derive to claims 15-16, 18, 20, 25-29 and 33.

As to the newly added claims 34-35, these claims depend from claim 18 and are thus similarly not obvious under Udipi, Rupp, and Kolluri, individually or in combination. Furthermore, none of Udipi, Rupp, and Kolluri discussed, suggested, or motivated the bonding of SODm on an implant device or on a pace maker component that can be implanted into a patient subcutaneously or intramuscularly.

Therefore Applicant respectfully requests the withdrawal of the Examiner's rejection.

Applicant believes the above remarks are fully responsive to the Office Action dated June 17, 2003. If the Examiner determines the prompt allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Mimi Dao at (408) 720-8300.

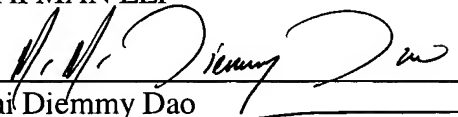
**Deposit Account Authorization**

Authorization is hereby given to charge our Deposit Account No. 02-2666 for any charges that may be due. Furthermore, if an extension is required, then Applicant hereby requests such extension.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR  
& ZAFMAN LLP

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